

Notice of Allowability	Application No.	Applicant(s)	
	10/714,724	RADHAKRISHNAN ET AL.	
	Examiner	Art Unit	
	Raymond Covington	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/28/05.
2. ☒ The allowed claim(s) is/are 1-16.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

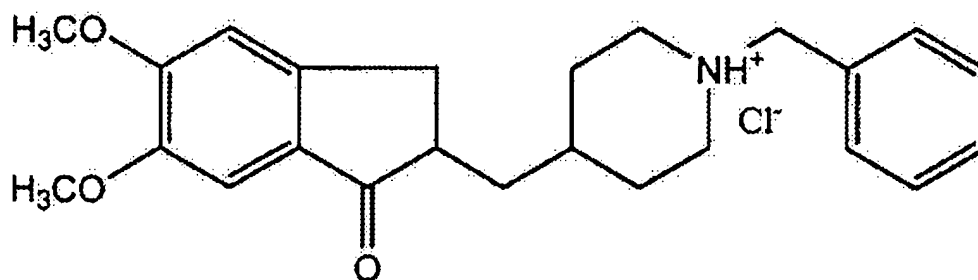
EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Connie Tong on 4/22/05.

The application has been amended as follows:

1. (Currently amended) A process for the preparation of 1-benzyl-4-[(5,6-dimethoxy-1-indanon)-2-yl] methylpiperidine hydrochloride (Donepezil HCl) of the Formula I

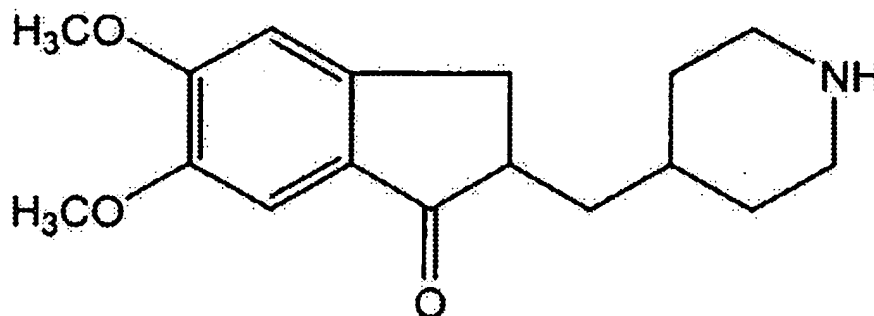


Formula I

comprising hydrogenating 5,6-dimethoxy-2-(pyridin-4-yl) methylene indan-1-one with a noble metal catalyst or a non-oxide derivative of a noble metal catalyst in [[dilute HCL or]] an organic solvent at 20-100° C and 10-90 psi gauge

pressure to form 4-[(5,6-dimethoxy-1-indanon)-2-yl] methyl piperidine of the

Formula II



Formula II

which is alkylated with an alkylating agent in an organic solvent at 20-80° C.

2. (Currently amended) The process according to Claim 1, wherein the organic solvent is selected from the group consisting of C₁-C₄ aliphatic alcohol, organic acid, ~~dilute HCL~~, ethyl acetate, aliphatic ketone, and mixtures thereof.

The following is an examiner's statement of reasons for allowance:

The rejections of record have been overcome in light of the filing of the Terminal Disclaimer, applicants' amendment of 2/28/05 and the examiner's amendment herein above with the patentable process parameters disclosed in the parent US 6,649,765.

Accordingly, claims 1-16 are allowed.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should

preferably accompany the issue fee. Such submissions should be clearly labeled
“Comments on Statement of Reasons for Allowance.”


Any inquiry concerning this communication or earlier communications from
the examiner should be directed to Raymond Covington whose telephone number
is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the
examiner’s supervisor, C. Tsang can be reached on (571) 272-0562. The fax
phone number for the organization where this application or proceeding is assigned
is 703-872-9306.

Information regarding the status of an application may be obtained from the
Patent Application Information Retrieval (PAIR) system. Status information for
published applications may be obtained from either Private PAIR or Public PAIR.
Status information for unpublished applications is available through Private PAIR
only. For more information about the PAIR system, see [http://pair-
direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system,
contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond Covington
Examiner
Art Unit 1625

RKC


CEILA CHANG
PRIMARY EXAMINER
GROUP 1200